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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/694,163  | 10/27/2003  | Michael Thomas Riebe | GR2351US5           | 3051             |
| 23347   | 7590        | 02/24/2006           | EXAMINER            |                  |
| GLAXOSMITHKLINE<br>CORPORATE INTELLECTUAL PROPERTY, MAI B475<br>FIVE MOORE DR., PO BOX 13398<br>RESEARCH TRIANGLE PARK, NC 27709-3398 |             |                      | HAGHIGHATIAN, MINA  |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1616                |                  |

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/694,163 | <b>Applicant(s)</b><br>RIEBE ET AL. |  |
|                              | <b>Examiner</b><br>Mina Haghighatian | <b>Art Unit</b><br>1616             |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/08/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/06/05 has been entered.

Receipt of the IDS filed on 06/08/05 is acknowledged. No claims are amended, cancelled or added. Accordingly claims 21-26 are pending.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purewal et al (5,225,183) in view of EP 0680752 A2.

Purewal et al teach a self-propelling aerosol formulation which comprises a medicament, 1,1,1,2-tetrafluoroethane and a surfactant. Suitable solid medicaments include salbutamol, and suitable salts of the drugs include sulphate (see col. 5, lines 52-66 and col. 6, lines 14-27). The particle size of the powder for inhalation is preferably in the range of 2 to 10 microns (col. 6, lines 42-45). Purewal lacks disclosure on the water content of the particulates.

EP 0680752 teaches water soluble substances such as drugs and excipients for administration by inhalation, having a particle size of less than 10 micron and having a stable crystalline form wherein the outer layer of crystals is not substantially amorphous or metastable (see abstract). The said Drugs include salbutamol sulphate and suitable excipient includes spray-dried lactose.

EP 0680752 also teaches that micronized drugs are dried in a stainless steel column with 200 mm diameter at 90 °C in vacuum for 23 hours. The dried substance is then cooled to about 30 °C and the pressure was normalized (page 4, lines 24-58).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the formulations and methods of Purewal on preparing powder formulations for inhalation comprising salbutamol sulphate by implementing teachings of EP 0680752 on heating, cooling, spray-drying and vacuum drying of particles to prepare dry powder formulations for inhalation with reasonable

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expectation of successfully preparing effective and easy to handle formulations which has a long shelf life.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

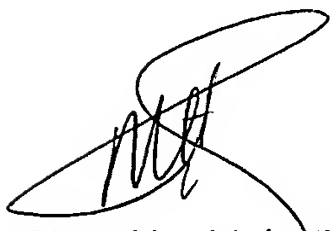
Claims 21-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-7 and 13-14 of U.S. Patent No. 6,656,453 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims would have been obvious over the reference claims. Specifically the reference claims are drawn to a process of preparing pharmaceutical aerosol formulations of annealed particulates of salbutamol sulphate. The instant claims are drawn to a metered dose inhaler comprising a

formulation of annealed particulates of salbutamol sulphate, and a method of treating a respiratory disorder comprising administering the said formulation to a patient. The metered dose inhaler and the method of treating a respiratory disorder are both disclosed in the specification of U.S. Patent No. 6,656,453 B2. Thus it is considered that metered dose inhaler and the method of treatment using the said composition are obvious over the process of forming the said formulations.

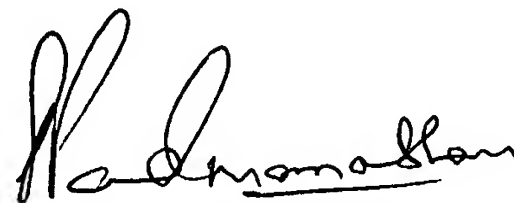
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian  
February 07, 2006



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER